Translation

PCT/JP2004/000605

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PH-1994-PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2004/000605	International filing date (*day/month/year*) 23 January 2004 (23.01.2004)	Priority date (*day/month/year*) 24 January 2003 (24.01.2003)
International Patent Classification (IPC) or national classification and IPC C12N 15/11, A61K 31/7105, A61P 31/14, A61K 48/00		
Applicant TOKYO METROPOLITAN ORGANIZATION FOR MEDICAL RESEARCH		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) disk, 1 , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

   ☒ Box No. I Basis of the report
   ☐ Box No. II Priority
   ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   ☒ Box No. IV Lack of unity of invention
   ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   ☐ Box No. VI Certain documents cited
   ☐ Box No. VII Certain defects in the international application
   ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23 January 2004 (23.01.2004)	26 November 2004 (26.11.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 7-10, 13

because:

☒ the said international application, or the said claim No. 13 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The invention of claim 13 concerns a method for treating the human body by therapy or surgery, which does not require an examination by the International Preliminary Examining Authority in accordance with PCT Article 34(2)(a)(i) and Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 7-10, 13.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

   See the Supplemental Box

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. Portions of claims 1-6, 11-12 other than the portions relating to claims 7-10 .

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	5	YES
	Claims	1-4, 6, 11-12	NO
Inventive step (IS)	Claims		YES
	Claims	1-6, 11-12	NO
Industrial applicability (IA)	Claims	1-6, 11-12	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: WO 95/30746 A1
Document 2: JP 7-303485 A
Document 3: WO 00/63364 A2

Claims 1-4, 6, 11 and 12

Document 1 describes an oligonucleotide that is essentially complementary to a portion of the hepatitis C virus RNA and an RNA molecule with a length of 22 nucleotides that contains a sequence selected from a group consisting of the specified sequence identification numbers (claims 25-50, SEQ ID NOS: 20 and 23).

Document 2 describes an antisense RNA to a partial sequence from the 5' non-translating region of the hepatitis C virus genome, a vector expressing the same, and a drug for the treatment of hepatitis that contains the same (claim 1).

The RNA molecules described in documents 1 and 2 are oligoribonucleotides that bind with sequence specificity to RNA of the hepatitis C virus.

As a result, the inventions of claims 1-4, 6, 11, and 12 are indistinguishable from the inventions described in documents 1 or 2.

Claim 5

The RNA that is essentially complementary to a part of the hepatitis C virus RNA described in documents 1 and 2 is not described as double stranded, and in that respect it differs from the invention of claim 5 of this application. However, document 3 describes the use of double stranded RNA for the purpose of inhibiting the virus polynucleotide and this examination finds that persons skilled in the art can easily make the RNA described in documents 1 and 2 double stranded.

Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purpose of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

** If item 4 in Box No. I applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box IV:

The oligoribonucleotides having the nucleotide sequences identified as SEQ ID NOS: 20-34 of claims 7 and 8 and the oligoribonucleotides having the nucleotide sequences identified as SEQ ID NOS: 47-55 of claims 9 and 10 have no common chemical structure, and the only point they have in common with the inventions of claims 1-6 and the other inventions of claims 7-10 is that they are oligoribonucleotides that bind with sequence specificity to the RNA of the hepatitis C virus.

However, document 1 describes an oligonucleotide that is essentially complementary to a portion of the hepatitis C virus RNA and an RNA molecule with a length of 12-28 nucleotides that contains a sequence selected from a group consisting of the specified sequence identification numbers (claims 25-50).

In addition, document 2 describes an antisense RNA to a partial sequence from the 5' non-translating region of the hepatitis C virus genome (claim 1).

The RNA molecules described in documents 1 and 2 are oligoribonucleotides that bind with sequence specificity to the RNA of the hepatitis C virus, and therefore, a substance that is an oligoribonucleotide that binds with sequence specificity to the RNA of the hepatitis C virus cannot considered a special technical feature as defined in PCT Rule 13.2.

As a result, this examination finds that among the inventions of claims 1-12, the inventions concerning the oligoribonucleotides having the nucleotide sequences identified as SEQ ID NOS: 20-34 of claims 7 and 8 and the oligoribonucleotides having the nucleotide sequences identified as SEQ ID NOS: 47-55 of claims 9 and 10 cannot be considered one group of inventions so linked as to form a single general inventive concept, and therefore they comprise a group of inventions consisting of 24 individual inventions, each of which concerns one of 24 different oligoribonucleotides.

Thus, all of the claims do not have a common special technical feature, and the inventions of claims 1-12 comprise a group of inventions consisting of a total of 25 individual inventions wherein are combined the inventions of claims 1-6, 11, and 12 that exclude those concerning the inventions of claims 7-10, and the group of inventions consisting of each of the 24 oligoribonucleotides identified as SEQ ID NOS: 20-34 and 47-55 among the inventions of claims 7-9 and the inventions of claims 10 and 11 that cite those claims.

Document 1: WO 95/30746 A1 (THE GENERAL HOSPITAL CORPORATION) November 16, 1995
Document 2: JP 7-303485 A (Tonen Corp.) November 21, 1995